

Minutes of Meeting

Alabama Medicaid Agency Pharmacy and Therapeutics Committee

May 3, 2023

Members Present: Dr. Lee Carter (Chairperson), Dr. Peter Hughes, Dr. Kelli Littlejohn Newman, Dr. Tiffany Lyght (Vice-Chairperson), Dr. Melinda Rowe, and Dr. George Sutton

Members Absent: Dr. Frances Heinze and Dr. Albert Holloway

Presenters: Dr. Rachel Bacon and Dr. Edward Pudim

1. OPENING REMARKS

Chairperson Carter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 1:05 p.m.

2. APPROVAL OF MINUTES

Chairperson Carter asked if there were any corrections to February 8, 2023 P&T Committee Meeting's minutes.

There were no corrections. Dr. Sutton made a motion to approve the minutes as presented and Dr. Hughes seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

Dr. Newman stated that ALERTs are included in the P&T member packets. The end of the Public Health Emergency (PHE) occurs on May 11th and several ALERTs have been sent related to this topic. Unwinding for the PHE will begin to require recipient signatures, and copays will not be put back into effect until October 2024. The MME edits will begin phasing down later this year. There is a new telemedicine policy going into effect which is available on the website.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations were explained. The drugs and

corresponding manufacturers are listed below with the appropriate therapeutic class. There was a total of one manufacturer verbal presentation at the meeting.

5. PHARMACOTHERAPY CLASS RE-REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy class reviews began at approximately 1:14 p.m. There were a total of 13 drug class re-reviews. The Anthelmintics, Aminoglycosides, Cephalosporins, Miscellaneous β -Lactam Antibiotics, Chloramphenicol, Macrolides, Penicillins, Quinolones, Sulfonamides, Tetracyclines, Antibacterials, Miscellaneous, Cerebral Stimulants/Agents Used for ADHD, and Wakefulness Promoting Agents were all last reviewed in May 2021.

Wakefulness Promoting Agents: American Hospital Formulary Service (AHFS) 282080

Manufacturer comments on behalf of these products:

Sunosi[®] - Axsome Therapeutics, Inc.

Dr. Bacon noted that the wakefulness promoting agents included in this review are listed in Table 1 on page 1131. Armodafinil and modafinil are currently available generically. Since the last review, Xywav[®] has gained approval for the treatment of idiopathic hypersomnia in adults. The 2021 American Academy of Sleep Medicine guidelines for the treatment of central disorders of hypersomnolence state that modafinil, pitolisant, sodium oxybate, and solriamfetol are recommended for the treatment of narcolepsy in adults. Armodafinil, dextroamphetamine, and methylphenidate are suggested for the treatment of narcolepsy in adults. Modafinil is recommended for the treatment of idiopathic hypersomnia in adults.

No brand wakefulness promoting agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee Members to mark their ballots.

Anthelmintics: AHFS 080800

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the anthelmintics included in this review are listed in Table 1 on page 8. All of the agents with the exception of mebendazole and triclabendazole are available in a generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand anthelmintic product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Aminoglycosides: AHFS 081202

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the aminoglycosides that are included in this review are listed in Table 1 on page 51. All of the aminoglycosides are available in a generic formulation, with the exception of amikacin inhalation suspension, plazomicin, and tobramycin inhalation powder. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand aminoglycosides product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Cephalosporins: AHFS 081206

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the cephalosporins that are included in this review are listed in Table 1 on page 143. All of the cephalosporins are available in a generic formulation with the exception of cefiderocol, ceftaroline, and the combination products.

Since the last review, ceftazidime-avibactam has gained approval for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in pediatric patients aged 3 months and older. Ceftolozane-tazobactam has gained approval for the treatment of complicated intra-abdominal infections (in combination with metronidazole) and complicated urinary tract infections, including pyelonephritis, in pediatric patients (birth to <18 years of age).

No brand cephalosporin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Miscellaneous β -Lactam Antibiotics: AHFS 081207

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the miscellaneous β -lactam antibiotics included in this review are listed in Table 1 on page 284. All of the injectable products are available in a generic formulation, with the exception of meropenem-vaborbactam and imipenem-cilastatin-relebactam. There have been

no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand miscellaneous β -lactam antibiotics product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Chloramphenicol: AHFS 081208

Manufacturer comments on behalf of these products:

None

Dr. Pudim commented that chloramphenicol is the only medication included in this review and is listed in Table 1 on page 388. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand chloramphenicol product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Macrolides: AHFS 081212

Manufacturer comments on behalf of these products:

None

Dr. Pudim commented that the macrolides included in this review are listed in Table 1 on page 406. There have been no major changes in prescribing information or clinical studies since the class was last reviewed. There is now a generic formulation of Erythrocin Lactobionate® (erythromycin lactobionate) in at least one dosage form or strength. In 2021, the Infectious Diseases Society of American and Society for Healthcare Epidemiology of American updated their clinical guidelines for the management of *Clostridium difficile* infection in adults, now recommending fidaxomicin as the standard therapy over vancomycin for patients with an initial or recurrent *Clostridium difficile* infection.

No brand macrolide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Penicillins: AHFS 081216

Manufacturer comments on behalf of these products:

None

Dr. Pudim commented that penicillins included in this review are listed in Table 1 on pages 502 and 503. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand penicillin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Quinolones: AHFS 081218

Manufacturer comments on behalf of these products:

None

Dr. Pudim commented that the quinolones included in this review are listed in Table 1 on page 631. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand quinolone is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Sulfonamides: AHFS 081220

Manufacturer comments on behalf of these products:

None

Dr. Pudim commented that the sulfonamides included in this review are listed in Table 1 on page 727. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand sulfonamide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Tetracyclines: AHFS 081224

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the tetracyclines included in this review are listed in Table 1 on page 792. All agents are available in a generic formulation with the exception of eravacycline and omadacycline. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

No brand tetracycline is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Chairperson Carter asked the P&T Committee members to mark their ballots.

Antibacterials, Miscellaneous: AHFS 081228

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the miscellaneous antibacterials are a diverse group of products that are used to treat many different types of infections. The Food and Drug Administration-approved indications vary depending on the particular agent and antimicrobial properties. It is important to analyze current treatment guidelines and published studies when making therapeutic decisions about the miscellaneous antibacterial agents. The miscellaneous antibacterials that are included in this review are listed in Table 1 on pages 870. Many agents in the class are available in a generic formulation. Oritavancin is now available as two branded products, Kimyrsa® and Orbactiv®. These products have differences in dose, strength, duration of infusion, and preparation instructions, including reconstitution and dilution instructions and compatible diluents. Orbactiv® is administered by intravenous infusion over three hours while Kimyrsa® is infused over one hour. These agents are indicated for the treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms.

Rifamycin (Aemcolo DR®) belongs to the ansamycin class of antibacterial drugs and acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase, blocking one of the steps in DNA transcription. This results in inhibition of bacterial synthesis and consequently growth of bacteria. Aemcolo DR® is indicated for the treatment of travelers' diarrhea caused by non-invasive strains of *Escherichia coli* in adults.

Additionally, dalbavancin has gained pediatric approval for the treatment of patients with acute bacterial skin and skin structure infections.

All brand miscellaneous antibacterials within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Bacitracin possesses an extensive adverse effect profile compared to the other brands and generics in the class.

No brand miscellaneous antibacterial is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Bacitracin should not be placed in preferred status regardless of cost.

Chairperson Carter asked the P&T Committee members to mark their ballots.

**Cerebral Stimulants/Agents for ADHD: Central Alpha-Agonists – AHFS 240816,
Amphetamine Derivatives – AHFS 282004, Respiratory and CNS Stimulants – AHFS 282032,
Central Nervous System Agents, Miscellaneous – AHFS 289200**

Manufacturer comments on behalf of these products:

None

Dr. Bacon noted that the cerebral stimulants/agents used for ADHD included in this review are listed in Table 1 beginning on page 1024. New agents have been approved since the last review.

Azstarys[®] (serdexmethylphenidate and dexamethylphenidate) is a central nervous system stimulant indicated for the treatment of ADHD in patients six years of age and older. Azstarys[®] capsules are co-formulated to contain 30% immediate-release dexamethylphenidate and 70% serdexmethylphenidate, a prodrug of dexamethylphenidate. Qelbree[®] (viloxazine) is a selective norepinephrine reuptake inhibitor indicated for the treatment of ADHD in adults and pediatric patients six years of age and older. The mechanism of viloxazine is similar to the norepinephrine modulation of atomoxetine, but with additional potential efficacy of serotonin modulation. Viloxazine is approved with a Black Box Warning related to concerns and risks of suicidal thoughts and behaviors. Xelstry[®] (dextroamphetamine) is indicated for the treatment of ADHD in adults and pediatric patients six years and older. Xelstry[®] is the first-and-only FDA approved transdermal amphetamine patch. There is also a methylphenidate patch (Daytrana[®]) approved for the treatment of ADHD.

No brand cerebral stimulant/agent used for ADHD is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Of note, shortages of multiple ADHD drugs are reported by the FDA, ASHP, and various news outlets. The direct cause of the shortages is unclear with sources citing a variety of reasons including supply constraints, unprecedented increase in demand, production issues, DEA regulations, and ingredient unavailability. Availability of ADHD medications differs by product but is generally expected to improve between late-April and late-June, based upon various data sources. Other state Medicaid plans are employing various strategies to help patients access medications through the shortage: for example, allowing short-term approvals for one-month for brand/generic substitution, allowing additional quantities of a lower strength to reach the dose that a patient needs with three-month overrides, and/or allowing temporary PA overrides for select specified agents.

Dr. Newman noted that many pharmacies are having difficulty acquiring these medications and the prescriber/pharmacy can call for a short-term override, which is determined on a case-by-case basis due to differing availability throughout the state. Dr. Hughes noted that this situation may improve as we enter the summer months and schools will be on break. Chairperson Carter asked the P&T Committee Members to mark their ballots.

6. RESULTS OF VOTING ANNOUNCED

The results of voting for each of the therapeutic classes were collected; all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

7. NEW BUSINESS

There was no new business.

8. NEXT MEETING DATE

The next P&T Committee Meetings are scheduled for August 2, 2023 and November 8, 2023.

9. ADJOURN

There being no further business, Dr. Carter moved to adjourn, and Dr. Hughes seconded. The meeting adjourned at 1:44 p.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
May 3, 2023

A. **Recommendation:** No brand anthelmintic product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Don Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie D Approve Approve as amended Disapprove No action
Commissioner

B. **Recommendation:** No brand aminoglycosides product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Don Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie D Approve Approve as amended Disapprove No action
Commissioner

C. Recommendation: No brand cephalosporin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRome, ms Approve Approve as amended Disapprove No action
Assistant Medical Director

Dr Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A Approve Approve as amended Disapprove No action
Commissioner

D. Recommendation: No brand miscellaneous β -lactam antibiotics product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRome, ms Approve Approve as amended Disapprove No action
Assistant Medical Director

Dr Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A Approve Approve as amended Disapprove No action
Commissioner

E. Recommendation: No brand chloramphenicol product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Don Am Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanette Approve Approve as amended Disapprove No action
Commissioner

F. Recommendation: No brand macrolide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Don Am Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanette Approve Approve as amended Disapprove No action
Commissioner

G. Recommendation: No brand penicillin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

A. Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Commissioner

H. Recommendation: No brand quinolone is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

A. Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Commissioner

I. Recommendation: No brand sulfonamide product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Dr. Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Commissioner

J. Recommendation: No brand tetracycline is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

Dr. Cur Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Commissioner

K. Recommendation: No brand miscellaneous antibacterial is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Bacitracin should not be placed in preferred status regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

MyRowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

An Cu Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A Approve Approve as amended Disapprove No action
Commissioner

L. Recommendation: No brand cerebral stimulant/agent used for ADHD is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

MyRowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

An Cu Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie A Approve Approve as amended Disapprove No action
Commissioner

M. Recommendation: No brand wakefulness promoting agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rowe, MD Approve Approve as amended Disapprove No action
Assistant Medical Director

M. CW Approve Approve as amended Disapprove No action
Deputy Commissioner

Stephanie Approve Approve as amended Disapprove No action
Commissioner

Respectfully submitted,

Rachel Bacon

5/4/2023

Rachel Bacon, PharmD, MPH

Date